

M/S. BIMAL PHARMA PVT. LTD . MUMBAI (INDIA)	FINISHED PRODUCT INFORMATIONS
QUALITY CONTROL AND ASSURANCE	PRODUCT : SUCRALFATE (USP)
MSDS no. BPPL 039	SPECIFICATION NO. FP-039

1. NOMENCLATURE : Sucralfate.  
: Sucrose Octasulfate-Aluminum  
Complex.  
: Beta-D-Fructofuranosyl-alpha-D-  
glucopyranoside octakis aluminum.  
: Sucrose Octakis (Hydrogen Sulphate)  
Aluminium Compound
2. CAS NO. : 54182-58-0
3. EMPIRICAL FORMULA :  $C_{12}H_{54}Al_{16}O_{75}S_8$   
or  
 $Al_8(OH)_{16}(C_{12}H_{14}O_{35}S_8) [Al(OH)_3]_x (H_2O)_y$
4. MOL. WT. : 1599.14 OR 2086.70
5. DESCRIPTION : White fine powder; Free flowing.
6. THERAPEUTIC USE : Used as an adjunctive treatment for stomach  
ulcers in humans.  
: Also used for the treatment of Gastro  
Esophageal Reflux Disease (GERD) and  
Stress ulcers.  
: For the treatment of active duodenal ulcers  
not related to NSAID usage.  
: Used in preparation of Tablets and  
Suspension.

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1. DESCRIPTION : White fine Powder;  
Free flowing.
2. SOLUBILITY : It is soluble in 2N Sulfuric acid.
3. IDENTIFICATION : A) By HPLC  
B) By Precipitates.  
C) By Reactions of Aluminium.
4. CLARITY & COLOUR OF SOLUTION : 10% Solution in 2N Sulfuric acid is Clear and practically colourless.  
(APPEARANCE OF SOLUTION)
5. HEAVY METALS : Not more than 0.002%.
6. PH : About 4.5
7. ORGANIC VOLATILE IMPURITY : Meets the requirement as per USP.
8. ARSENIC : NMT 4 ppm
9. CHLORIDE CONTENT : NMT 0.5%
10. FREE ALUMINIUM CONTENT : NMT 0.5%

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11. FREE SUCROSE CONTENT : NMT 0.2%
12. PYRIDINE & 2-METHYL PYRIDINE : Each NMT 0.05%
13. RELATED SUBSTANCES : NMT 0.1%.
14. ACID NEUTRALISATION EQUIVALENT (mEq/g) : NLT 12.0
15. ASSAY (ODB) :
- a)  $C_{12}H_{14}O_{35}S_8$  : 30.0% - 38.0%
- b) Aluminium : 15.5% - 18.5%
16. JEL TEST : Form Jel with Water.